(4) The claim may indicate that it is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), Government Printing Office.

(5) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or ''Nutrition and Your Health: Dietary Guidelines for Americans,'' USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between substances in diets low in fat and high in fruits and vegetables and cancer:

(1) Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C.

[58 FR 2639, Jan. 6, 1993]

§ 101.79 Health claims: Folate and neural tube defects.

(a) *Relationship between folate and neural tube defects*—(1) *Definition.* Neural tube defects are serious birth defects of the brain or spinal cord that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of neural tube defects and account for about 90 percent of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

(2) *Relationship.* The available data show that diets adequate in folate may reduce the risk of neural tube defects. The strongest evidence for this relationship comes from an intervention study by the Medical Research Council of the United Kingdom that showed that women at risk of recurrence of a neural tube defect pregnancy who consumed a supplement containing 4 milligrams (mg)(4,000 micrograms (mcg)) folic acid daily before conception and continuing into early pregnancy had a reduced risk of having a child with a neural tube defect. (Products containing this level of folic acid are drugs). In addition, based on its review of a Hungarian intervention trial that reported periconceptional use of a multivitamin and multimineral preparation containing 800 mcg (0.8 mg) of folic acid, and its review of the observational studies that reported periconceptional use of multivitamins containing 0 to 1,000 mcg of folic acid, the Food and Drug Administration concluded that most of these studies had results consistent with the conclusion that folate, at levels attainable in usual diets, may reduce the risk of neural tube defects.

(b) *Significance of folate*—(1) *Public health concern.* Neural tube defects occur in approximately 0.6 of 1,000 live births in the United States (i.e., approximately 6 of 10,000 live births; about 2,500 cases among 4 million live births annually). Neural tube defects are believed to be caused by many factors. The single greatest risk factor for a neural tube defect-affected pregnancy is a personal or family history of a pregnancy affected with a such a defect. However, about 90 percent of infants with a neural tube defect are born to women who do not have a family history of these defects. The available evidence shows that diets adequate in folate may reduce the risk of neural tube defects but not of other birth defects.

(2) *Populations at risk.* Prevalence rates for neural tube defects have been reported to vary with a wide range of factors including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race,

nutrition, and maternal health, including maternal age and reproductive history. Women with a close relative (i.e., sibling, niece, nephew) with a neural tube defect, those with insulin-dependent diabetes mellitus, and women with seizure disorders who are being treated with valproic acid or carbamazepine are at significantly increased risk compared with women without these characteristics. Rates for neural tube defects vary within the United States, with lower rates observed on the west coast than on the east coast.

(3) *Those who may benefit.* Based on a synthesis of information from several studies, including those which used multivitamins containing folic acid at a daily dose level of ≤400 mcg (≤0.4 mg), the Public Health Service has inferred that folate alone at levels of 400 mcg (0.4 mg) per day may reduce the risk of neural tube defects. The protective effect found in studies of lower dose folate measured by the reduction in neural tube defect incidence, ranges from none to substantial; a reasonable estimate of the expected reduction in the United States is 50 percent. It is expected that consumption of adequate folate will avert some, but not all, neural tube defects. The underlying causes of neural tube defects are not known. Thus, it is not known what proportion of neural tube defects will be averted by adequate folate consumption. From the available evidence, the Public Health Service estimates that there is the potential for averting 50 percent of cases that now occur (i.e., about 1,250 cases annually). However, until further research is done, no firm estimate of this proportion will be available.

(c) *Requirements.* The label or labeling of food may contain a folate/neural tube defect health claim provided that:

(1) *General requirements.* The health claim for a food meets all of the general requirements of §101.14 for health claims, except that a food may qualify to bear the health claim if it meets the definition of the term ''good source.''

(2) *Specific requirements*—(i) *Nature of the claim*—(A) *Relationship.* A health claim that women who are capable of becoming pregnant and who consume adequate amounts of folate daily during their childbearing years may reduce their risk of having a pregnancy affected by spina bifida or other neural tube defects may be made on the label or labeling of food provided that:

(B) *Specifying the nutrient.* In specifying the nutrient, the claim shall use the terms ''folate,'' ''folic acid,'' ''folacin,'' ''folate, a B vitamin,'' ''folic acid, a B vitamin,'' or ''folacin, a B vitamin.''

(C) *Specifying the condition.* In specifying the health- related condition, the claim shall identify the birth defects as ''neural tube defects,'' ''birth defects spina bifida or anencephaly,'' ''birth defects of the brain or spinal cord anencephaly or spina bifida,'' ''spina bifida and anencephaly, birth defects of the brain or spinal cord,'' ''birth defects of the brain or spinal cord;'' or ''brain or spinal cord birth defects.''

(D) *Multifactorial nature.* The claim shall not imply that folate intake is the only recognized risk factor for neural tube defects.

(E) *Reduction in risk.* The claim shall not attribute any specific degree of reduction in risk of neural tube defects from maintaining an adequate folate intake throughout the childbearing years. The claim shall state that some women may reduce their risk of a neural tube defect pregnancy by maintaining adequate intakes of folate during their childbearing years. Optional statements about population-based estimates of risk reduction may be made in accordance with paragraph (c)(3)(vi) of this section.

(F) *Safe upper limit of daily intake.* Claims on foods that contain more than 100 percent of the Daily Value (DV) (400 mcg) when labeled for use by adults and children 4 or more years of age, or 800 mcg when labeled for use by pregnant or lactating women) shall identify the safe upper limit of daily intake with respect to the DV. The safe upper limit of daily intake value of 1,000 mcg (1 mg) may be included in parentheses.

(G) *The claim.* The claim shall not state that a specified amount of folate per serving from one source is more effective in reducing the risk of neural tube defects than a lower amount per serving from another source.

(H) The claim shall state that folate needs to be consumed as part of a healthful diet.

(ii) *Nature of the food*—(A) *Requirements.* The food shall meet or exceed the requirements for a ''good source'' of folate as defined in § 101.54;

(B) *Dietary supplements.* Dietary supplements shall meet the United States Pharmacopeia (USP) standards for disintegration and dissolution, except that if there are no applicable USP standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.

(iii) *Limitation.* The claim shall not be made on foods that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D per serving or per unit.

(iv) *Nutrition labeling.* The nutrition label shall include information about the amount of folate in the food. This information shall be declared after the declaration for iron if only the levels of vitamin A, vitamin C, calcium, and iron are provided, or in accordance with § 101.9 (c)(8) and (c)(9) if other optional vitamins or minerals are declared.

(3) *Optional information*—(i) *Risk factors.* The claim may specifically identify risk factors for neural tube defects. Where such information is provided, it may consist of statements from § 101.79(b)(1) or (b)(2) (e.g., Women at increased risk include those with a personal history of a neural tube defect-affected pregnancy, those with a close relative (i.e., sibling, niece, nephew) with a neural tube defect; those with insulin-dependent diabetes mellitus; those with seizure disorders who are being treated with valproic acid or carbamazepine) or from other parts of this paragraph (c)(3)(i).

(ii) *Relationship between folate and neural tube defects.* The claim may include statements from paragraphs (a) and (b) of this section that summarize the relationship between folate and neural tube defects and the significance of the relationship except for information specifically prohibited from the claim.

(iii) *Personal history of a neural tube defect-affected pregnancy.* The claim may state that women with a history of a neural tube defect pregnancy should consult their physicians or health care providers before becoming pregnant. If such a statement is provided, the claim shall also state that all women should consult a health care provider when planning a pregnancy.

(iv) *Daily value.* The claim may identify 100 percent of the DV (100% DV; 400 mcg) for folate as the target intake goal.

(v) *Prevalence.* The claim may provide estimates, expressed on an annual basis, of the number of neural tube defect-affected births among live births in the United States. Current estimates are provided in § 101.79(b)(1), and are approximately 6 of 10,000 live births annually (i.e., about 2,500 cases among 4 million live births annually). Data provided in § 101.79(b)(1) shall be used, unless more current estimates from the U.S. Public Health Service are available, in which case the latter may be cited.

(vi) *Reduction in risk.* An estimate of the reduction in the number of neural tube defect-affected births that might occur in the United States if all women consumed adequate folate throughout their childbearing years may be included in the claim. Information contained in paragraph (b)(3) of this section may be used. If such an estimate (i.e., 50 percent) is provided, the estimate shall be accompanied by additional information that states that the estimate is population-based and that it does not reflect risk reduction that may be experienced by individual women.

(vii) *Diets adequate in folate.* The claim may identify diets adequate in folate by using phrases such as ''Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.'' or ''Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables, legumes, whole grain products, fortified cereals, or dietary supplements.'' or ''Adequate amounts of folate can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables, legumes, whole grain products, including breads, rice, and pasta, fortified cereals, or a dietary supplement.''

(d) *Model health claims.* The following are examples of model health claims that may be used in food labeling to

describe the relationship between folate and neural tube defects:

(1) *Examples 1 and 2.* Model health claims appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit (general population). The examples contain only the required elements:

(i) Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(ii) Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(2) *Example 3.* Model health claim appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit. The example contains all required elements plus optional information: Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

(3) *Example 4.* Model health claim appropriate for foods intended for use by the general population and containing more than 100 percent of the DV of folate per serving or per unit: Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV (1,000 mcg).

[61 FR 8779, Mar. 5, 1996]

EFFECTIVE DATE NOTE: At 61 FR 8779, Mar. 5, 1996, § 101.79 was revised, effective April 19, 1996. For the convenience of the reader, the superseded text is set forth below.

§ 101.79 Health claims: folate and neural tube defects.

(a) *Relationship between folate and neural tube defects*—(1) *Definition.* Neural tube defects are serious birth defects of the brain or spinal cord that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of neural tube defects and account for about 90 percent of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

(2) *Relationship.* The available data show that diets adequate in folate may reduce the risk of neural tube defects. The strongest evidence for this relationship comes from an intervention study by the Medical Research Council of the United Kingdom that showed that women at risk of recurrence of a neural tube defect pregnancy who consumed a supplement containing 4 milligrams (mg) (4,000 micrograms (µg)) folic acid daily had a reduced risk of having a child with a neural tube defect. (Products that contain this level of folic acid are drugs.) In addition, based on its review of a Hungarian intervention trial that used a multivitamin and multimineral preparation containing 800 µg (0.8 mg) of folic acid, and its review of the observational studies that reported use of multivitamins containing 0 to 1,000 µg of folic acid, the Food and Drug Administration concluded that most of these studies had results consistent with the conclusion that folate, at levels attainable in usual diets, may reduce the risk of neural tube defects.

(b) *Significance of folate*—(1) *Public health concern.* Neural tube defects occur in approximately 0.6 of 1,000 live births in the United States (i.e., about 2,500 cases among 4 million live births annually). Neural tube defects are believed to be caused by many factors. The single greatest risk factor for a neural tube defect-affected pregnancy is a personal or family history of a pregnancy affected with a such a defect. However, about 90 percent of infants with a neural tube defect are born to women who do not have a family history of these defects. The available evidence shows that diets adequate in folate may reduce the risk of neural tube defects but not of other birth defects.

(2) *Populations at risk.* Prevalence rates for neural tube defects have been reported to vary with a wide range of factors, including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health, including maternal age and reproductive history. Women with a close relative (i.e., sibling, niece, nephew) with a neural tube defect, those with insulin-dependent diabetes mellitus, and women with seizure disorders who are being treated with valproic acid or carbamazepine are at significantly increased risk compared with women without these characteristics. Rates for neural tube defects vary within the United States, with lower rates observed on the west coast than on the east coast.

(3) *Those who may benefit.* Based on a synthesis of the results of several observational studies, the Public Health Service has estimated that about 50 percent of neural tube defect-affected pregnancies in the United

States (e.g., about 1,250) may be averted annually if all women consume adequate amounts of folate daily (i.e., 0.4 mg) throughout their childbearing years.

(c) *Requirements.* The label or labeling of food in conventional food form or dietary supplements may contain a folate/neural tube defect health claim provided that:

(1) *General requirements.* The health claim for a food or supplement meets all of the general requirements of §101.14 for health claims, except that a food or dietary supplement may qualify to bear the health claim if it meets the definition of the term ''good source.''

(2) *Specific requirements*—(i) *Nature of the claim*—(A) *Relationship.* A health claim that women who are capable of becoming pregnant and who consume adequate amounts of folate daily during their childbearing years may reduce their risk of having a pregnancy affected by spina bifida or other neural tube defects may be made on the label or labeling of foods in conventional food form or of dietary supplements provided that:

(B) *Specifying the nutrient.* In specifying the nutrient, the claim shall use the terms ''folate,'' ''folic acid,'' ''folacin,'' ''folate, a B vitamin,'' ''folic acid, a B vitamin,'' or ''folacin, a B vitamin.''

(C) *Specifying the condition.* In specifying the health-related condition, the claim shall identify the birth defects as ''neural tube defects,'' ''birth defects, spina bifida, or anencephaly,'' ''birth defects of the brain or spinal cord anencephaly or spina bifida,'' or ''spina bifida or anencephaly, birth defects of the brain or spinal cord;''

(D) *Multifactorial nature.* The claim shall state that neural tube defects have many causes and shall not imply that folate intake is the only recognized risk factor for neural tube defects.

(E) *Prevalence.* In specifying the prevalence of neural tube defects among women in the general population, the claim shall state that such birth defects ''which, while not widespread, are extremely significant'' or ''* * birth defects * * * that, while not widespread, are extremely significant.''

(F) *Reduction in risk.* The claim shall not attribute any specific degree of reduction in risk of neural tube defects, including mention of the Public Health Service estimate that 50 percent of neural tube defects may be averted annually, to maintaining an adequate folate intake throughout the childbearing years. The claim shall state that some women may reduce their risk of a neural tube defect pregnancy by maintaining adequate intakes of folic acid during their childbearing years.

(G) *Safe upper limit of daily intake.* Claims on fortified foods in conventional form and on dietary supplements that contain more than 25 percent of the RDI for folate (100 µg per serving or per unit) shall state that 1 mg folate per day is the safe upper limit of intake (e.g., ''Folate consumption should be limited to 1,000 µg per day from all sources.'')

(H) *The claim.* The claim shall not state that a specified amount of folate (e.g., 400 µg in a dietary supplement) is more effective in reducing the risk of neural tube defects than a lower amount (e.g., 100 µg in a breakfast cereal or from diets rich in fruits and vegetables).

(ii) *Nature of the food*—(A) *Requirements.* The food or supplement shall meet or exceed the requirements for a good source of folate as defined in §101.54;

(B) *Diets adequate in folate.* The claim shall identify diets adequate in folate by using phrases such as ''* * * diets that include 2 to 4 servings per day of fruits) including citrus fruits and juices), 3 to 5 servings of vegetables (including dark green leafy vegetables and legumes), 6 to 11 servings of enriched grain products (such as breads, rice, and pasta) and fortified cereals. Such diets provide many essential minerals and vitamins, including folate. Women who do not eat well-balanced diets or who may be concerned about their diets may choose to obtain folate from dietary supplements.''; or ''Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables and legumes, enriched grain products, including breads, rice, and pasta, fortified cereals, or a dietary supplement.''; or ''Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or from dietary supplements.''

(C) *Dietary supplements.* Dietary supplements shall meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution, except that if there are no applicable U.S.P. standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.

(iii) *Limitation.* The claim shall not be made on foods in conventional food form or dietary supplements that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D.

(iv) *Nutrition labeling.* The nutrition label shall include information about the amount of folate in the food. This information shall be declared after the declaration for iron if only the levels of vitamin A, vitamin C, calcium, and iron are provided, or in accordance with §101.9(c)(8) and (c)(9) if other optional vitamins or minerals are declared.

(3) *Optional information*—(i) *Risk factors.* The claim may specifically identify risk factors for neural tube defects;

(ii) *Relationship between folate and neural tube defects.* The claim may include statements from paragraphs (a) and (b) of this

section that summarize the relationship between folate and neural tube defects and the significance of the relationship except for information specifically prohibited from the claim.

(iii) *Personal history of a neural tube defect-affected pregnancy*. The claim may state that women with a history of a neural tube defect pregnancy should consult their physicians or health care providers before becoming pregnant.

(iv) *Daily value*. The claim may identify the daily value level of 400 µg of folate per day as the target intake goal.

(d) *Model health claims*. The following are examples of model health claims that may be used in food labeling to describe the relationship between folate and neural tube defects:

(1) *Example 1*. Women who consume adequate amounts of folate, a B vitamin, daily throughout their childbearing years may reduce their risk of having a child with a neural tube birth defect. Such birth defects, while not widespread, are very serious. They can have many causes. Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or a supplement. Folate consumption should be limited to 1,000 µg per day from all sources.

(2) *Example 2*. Women who consume adequate amounts of folate daily throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain and spinal cord. Such birth defects, while not widespread, are very serious. They can have many causes. Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or a supplement. Women who have had a child with a spinal cord birth defect should consult a physician before becoming pregnant. Folate consumption should be limited to 1,000 µg per day from all sources.

(3) *Example 3*. Women who take steps to ensure that their folate intake is adequate throughout their childbearing years may reduce their risk of having a child with a neural tube defect. Such birth defects, while not widespread, are very serious. They can have many causes. Adequate amounts of folate, a B vitamin, can be obtained from diets rich in citrus fruits and juices, dark green leafy vegetables and legumes, enriched grain products such as breads, rice, and pasta, fortified cereal, or a supplement. Folate consumption should be limited to 1,000 µg per day from all sources.

(4) *Example 4*. Women who take steps to ensure that their folate intake is at least 400 µg daily throughout their childbearing years may reduce their risk of having a child with spina bifida or anencephaly, birth defects of the brain or spinal cord that, while not widespread, are very serious. These birth defects can have many causes. Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables and legumes, enriched grain products, including breads, rice, and pasta, fortified cereals, or from a supplement. Women who have had a pregnancy affected with a neural tube defect should consult a physician before becoming pregnant. Folate consumption should be limited to 1,000 µg per day from all sources.

(5) *Example 5*. Some women who consume the Daily Value of folate (400 µg) throughout their childbearing years may reduce their risk of having a child affected with spina bifida or anencephaly, birth defects of the brain or spinal cord that, while not widespread, are very serious. These birth defects can have many causes. Women of childbearing age should choose well-balanced diets that include 2 to 4 servings per day of fruits (including citrus fruits and juices), 3 to 5 servings of vegetables (including dark green leafy vegetables and legumes), 6 to 11 servings of enriched grain products (such as breads, rice, and pasta) or fortified cereals throughout their childbearing years. Such diets provide many essential minerals and vitamins, including folate. Women who may be concerned about their diets may choose to obtain folate from a supplement. Folate consumption should be limited to 1,000 µg per day from all sources.

(e) *Effective date*. For fortified foods, this regulation is effective on the date the food additive regulation on the use of folic acid that was proposed on October 14, 1993, becomes effective.

[59 FR 434, Jan. 4, 1994]

Subpart F—Specific Requirements for Descriptive Claims that are Neither Nutrient Content Claims nor Health Claims

§ 101.95 "Fresh," "freshly frozen," "fresh frozen," "frozen fresh."

The terms defined in this section may be used on the label or in labeling of a food in conformity with the provisions of this section. The requirements of the section pertain to any use of the subject terms as described in paragraphs (a) and (b) of this section that expressly or implicitly refers to the food on labels or labeling, including use in a brand name and use as a sensory modifier. However, the use of the term ''fresh'' on labels or labeling is not subject to the requirements of